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Meta-analysis of efficacy and safety of ulinuzumab in the treatment of moderate to severe active Crohn's disease

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 November 2023 and was last updated on 24 November 2023.

INTRODUCTION

Review question / Objective To conduct a meta-analysis on the efficacy and safety of ustekinumab in the therapy of moderately to severely active Crohn's illness.

Condition being studied Using the method of combining subject words and free words, a systematic search was conducted on the efficacy and effectiveness of ustekinumab in the therapy of moderate to seriously active Crohn's illness in CNKI, VIP, Wanfang, ScienceNet, Pubmed and other literatures. For the original safety literature, two researchers were selected to independently evaluate the quality of the included literature according to the Jadad modified scoring scale, and the meta-analysis was processed through RevMan software.

METHODS

Participant or population ustekinumab in the therapy of moderate to seriously active Crohn's illness in CNKI, VIP, Wanfang, ScienceNet, Pubmed and other literatures.

Intervention The experimental group used ustekinumab, and the control group used placebo.

Comparator Ustekinumab in the therapy of moderate to seriously active Crohn's illness.

Study designs to be included By searching the Embase database, 678 documents were initially obtained . After removing duplicate documents, 315 articles were obtained. After excluding reviews, systematic reviews, reviews and animal experiments, 227 articles were obtained. After

browsing the abstracts, 11 documents were included.

Eligibility criteria (1) The type of research is a randomized controlled research, which does not limit the use of blinding ; (2) For patients clinically diagnosed with moderately to seriously active Crohn's illness, a CD activity index of ≥15 is classified as active stage, and a CD activity index of 221 to 450 is classified as active stage. Moderate, and a score of 450 or above is considered severe; (3) The patient has clear consciousness and normal cognition; (4) The sufferer is over 18 years old, complete clinical data; (5) The patient and his family members sign informed consent; (6) The study subjects were all confirmed sufferers with moderate to seriously active Crohn's illness; (7) Intervention measures: the experimental group used ustekinumab , and the control group used placebo; (8) All patients had relevant outcome indicators.

Information sources Ustekinumab in the therapy of moderately to seriously active Crohn's illness in CNKI, VIP, Wanfang, ScienceNet, Pubmed , etc. original documents. The search will be conducted in Chinese and English until October 2023. Chinese search terms include keywords including “ustekinumab”, “Crohn’s disease”, “moderate-severe activity”, etc. To ensure a comprehensive search, we also searched the Cochrane Library and Scopus databases. In the process of screening literature, we followed the following process: first, we screened the retrieved literature to remove researches that did not match the inclusion criteria; then, we read the abstracts and full texts of the screened literature to further determine whether they met the inclusion criteria; Finally, data from studies that matched the inclusion criteria were extracted.

Main outcome(s) Literature screening: Based on the inclusion and exclusion criteria, two researchers were selected to independently screen the literature, including three stages: initial screening, re-screening and cross-checking. If it is a disagreement between the 2 researchers, they can discuss it together and resolve it, or have a third researcher step in and make a decision. The content of data extraction includes: (1) Main features of the included literature, including title, author, publication year, sample size, etc.; (2) Baseline data of research subjects: including age, gender composition, disease course, intervention measures, etc.

Quality assessment / Risk of bias analysis Meta-analysis is processed by RevMan software. Count data are expressed as relative risk (RR) effect statistics , and the corresponding 95% confidence interval (CI) is calculated and represented by forest plot ; Heterogeneity among the results of each study was tested using χ^2. If P> 0.10, I2 <50% , the studies were homogeneous , and the fixed impacts model was selected; If P50%, it indicates clear statistical heterogeneity in the included research. Choosing a random impacts model, and if necessary, using sensitivity analysis to observe changes in heterogeneity and effect values to determine the stability of the synthesized outcomes.

Strategy of data synthesis Two researchers were selected to independently evaluate the quality of the included literature according to the Jadad modified rating scale, which mainly includes four aspects: random sequence generation, randomization concealment, blinding, withdrawal, and withdrawal. The total score is 5 points, of which 1-2 are considered low-quality documents and 3-5 are considered high-quality documents.

Subgroup analysis A total of 6 documents reported clinical response rates, and it had no heterogeneity between the randomized trials (I 2 =96%, P = <0.01. Fixed impacts analysis was used. The meta-analysis outcomes showing that compare to the placebo control one, the clinical response ratio of ulinuzumab in the therapy of moderate to seriously active Crohn's illness is relatively high.

Sensitivity analysis A total of 5 documents reported the clinical remission rate, and it had no heterogeneity between the randomized trials (I 2 =42, P =0.12). Fixed impact analysis was used. The meta-analysis outcomes showing that, compared with the placebo control group, Usteinol Monoclonal antibody treatment has a greater remission rate in clinic in moderately to seriously active Crohn's illness (OR=2.00, 95%CI: 1.70~2.36, P <0.001)..

Country(ies) involved China.

Keywords ustekinumab; moderate-severe; active Crohn's disease; efficacy; safety; Meta-analysis.

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